

K053181

510(k) Summary

APR 27 2006

Application Date:	November 14, 2005
Submission Type:	Traditional 510(k)
Applicant Manufacturing Address:	AGA Medical Corporation 682 Mendelssohn Avenue Golden Valley, Minnesota 55427
Contact Person:	Patricia A. LaForte Regulatory Affairs Associate
Establishment Registration Number:	2135147
Device Classification Name:	Wire, Guide, Catheter
Device Common/Usual Name:	Guidewire
Device Proprietary Name:	AMPLATZER® Noodlewire Guidewire
Device Classification:	Class II, Reviewed by Cardiovascular
Device Product Code:	DQX
Reason for 510(k):	New Device Submission
Equivalence Device Comparison:	Lake Region Manufacturing Guidewire
Performance Standards:	Performance standards have not been promulgated to date for these devices

Device Description

The AMPLATZER Noodlewire Guidewire is a guidewire comprised of a stainless steel cable and coil. The cable wire component forms the inner body of the guidewire. The outer layer of the guidewire consists of a flat wire component coated with PTFE. The cable is placed within the coil. All components are secured together forming a single guidewire.

Intended Use

The AMPLATZER Noodlewire Guidewire is intended for percutaneous vessel entry typically using the Seldinger technique to facilitate subsequent introduction of an intravascular device.

Technological Characteristics as Compared to Predicate Device

The AMPLATZER Noodlewire Guidewire is constructed from the same biocompatible materials, coated with polytetrafluoroethylene (PTFE), packaged / sterilized utilizing the same materials / methods, and have the same principle of use as the predicate device.

Summary of Studies:

A. Functional Testing

In-vitro testing was conducted in accordance with ISO 11070, Sterile single-use intravascular catheter introducers and FDA Coronary and Cerebrovascular Guidewire Guidance, January, 1995. The AMPLATZER Noodlewire samples were subjected to kink, torqueability, torque strength, corrosion, fracture, flexure, tip flexibility, lubricity, and pull testing.

In-vitro Simulated Life Testing to document performance of the AMPLATZER Noodlewire Guidewire under simulated, but accelerated, in-use conditions was performed.

Biocompatibility testing was completed per ISO 10993-1.

B. Clinical Studies

The AMPLATZER Noodlewire Guidewire was used as a part of a feasibility clinical trial conducted in the United States. Specific data to the Noodlewire Guidewire was collected as part of the clinical trial.

C. Conclusions Drawn from the Studies

The results of the testing indicated that the AMPLATZER Noodlewire Guidewire functions according to specifications and the materials used in the Noodlewire Guidewire are biocompatible. Therefore, the Noodlewire Guidewire is considered acceptable for human use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2006

AGA Medical Corporation
c/o Ms. Patricia A. LaForte
Regulatory Affairs Associate
682 Mendelssohn Avenue
Golden Valley, MN 55427

Re: K053187
AMPLATZER® Noodlewire Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guidewire
Regulatory Class: II
Product Code: DQX
Dated: March 24, 2006
Received: March 27, 2006

Dear Ms. LaForte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Bram D. Zuckerman



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: 12053187

Device Name: **AMPLATZER® Noodlewire Guidewire**

Indications for Use: The AMPLATZER Noodlewire Guidewire is intended for percutaneous vessel entry typically using the Seldinger technique to facilitate subsequent introduction of an intravascular device.

Prescription Use ☒ AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use ☐
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Donna R. Vadney
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number 12053187